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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,726	06/30/2006	Mark C. Poznansky	62063(51588)	1191

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EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,726	Applicant(s) POZNANSKY ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,29,35,37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 29,37 and 39-44 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Examiner assigned to your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656 and the examiner signed below.

Claim Status

2. The amendments to the claims filed 10 February 2009 is acknowledged. Applicants have cancelled claims 30-34, 36 and 38 Claims 1. Thus, claims 1, 29, 35, 37 and 39-44 are pending and subject to examination.

Allowable Subject matter

3. Claim 1 remains allowable for the reasons recited in the previous Office action.

Withdrawal of Previous Rejections

4. The rejection of claims 29-33, 36, 38 and 42-44 as being anticipated by Srivastava et al. (WO 01/52791 and evidenced by US Patent 5,759,119) is withdrawn in view of the amendments to the claims which incorporate claims which were not previously rejected by the noted reference (e.g. dependent claims 34, 35, 37, 39, 40 and 41, wherein said claims were objected).

New Rejections - Necessitated by Amendments

Claim Rejections - 35 USC § 112 – 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 43 and 44 recites the limitation "the method of claim 29, wherein the hematopoietic cells are immune cells (claim 43)" or "The method of claim 29, wherein the immune cells are T cells (claim 44)". There is insufficient antecedent basis for this limitation in the claim because claim 29 does not recite hematopoietic cells or immune cells.

New Rejections – Not Necessitated by Amendments

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 29, 37, 39, 40 and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al. (WO 01/017554).

Srivastava teaches pharmaceutical compositions comprising of heat shock proteins (HSPs), complexed and non-complexed, which are administered to patients in need thereof used in the prevention and treatment of graft rejections, e.g. organs and tissue graft rejection (see for example Abstract), wherein said treatment is used to

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suppress said patients immune response. (instant claims 29, 37, 39, 42-44 where SEQ ID NO:3 is human hsp90 protein and is used in methods as immunotherapeutic agent, for example).

Specifically, the heat shock proteins which can be used are for example, human heat shock protein (see for example, p. 8, lines 3-8 AND wherein said hsp90 can be recombinant human hsp90 such as GenBank X15183 (see p. 21, lines 6-13) - it is noted that instant SEQ ID NO: 3 and said human hsp90 such as GenBank X15183 are 100% identical (see attached sequence alignment)).

Although, the reference does not teach the fugetactic activity per se, it would be the inherent property of human hsp90 such as GenBank X15183 to promote fugetactic activity because the said protein is identical to the instant SEQ ID NO:3.

Thus, if the amino structure of a peptide is identical, then the function must also be the same. Therefore, finding of a new function of the well known polypeptide, here HSP90 protein as being able to promote fugetaxis of migratory cells, is non-patentable by itself.

Routes of administration can include local and systemic administration (see p. 33, lines 12-13) – (instant claims 39 and 40).

Srivastava et al. teach that Heat shock proteins elicits a T-cell response against the tissue of donor (see p. 38, lines 25-35), (instant claims 42-44 where the cells affected by immune response are T cells).

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With regard to instant claim 37 and said autoimmune reaction being at or near a joint, it is noted the transplantation of cartilage tissue (see p. 12, Section 5.1) is commonly performed in joint areas such as knee joints.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Srivastava et al. (WO 01/017554) as applied to claims 29, 37, 39, 40 and 42-44 above, and further in view of Robbins et al. (US 2003/0104622).

The teachings of Srivastava et al. are set forth above. Briefly, Srivastava et al. teach HSP90 protein that is 100% identical to instant SEQ ID NO: 3 which is used in a method to prevent the rejection of organs or tissue grafts/transplants in patients by administering to said patients a therapeutic effective amount of said HSP90. Although, the reference does not teach the fugetactic activity per se, it would be the inherent property of human hsp90 such as GenBank X15183 to promote fugetactic activity because the said protein is identical to the instant SEQ ID NO:3.

Srivastava et al., however, do not teach attaching said HSP90 to a targeting molecule.

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Robbins et al. teach internalizing peptides (also referred to as protein transduction domains-PTDs) which are capable of facilitating the delivery, uptake and, where desired, nuclear and/or cytoplasmic transport of cargo (e.g. polynucleotides, polypeptides, small molecules, virus, modified virus, plasmid, etc.) into a target cell. (see paragraphs 0014-0015) The PTD's offer distinct advantages over other targeting molecules such as viral vectors as it is noted that the cell recognition specificity of viruses and viral vectors is generally very high, and their ability to transfer genetic material into a target cell makes them particularly attractive candidates for the delivery of cargo to a target cell. However, there are potential risks and limitations associated with the use of viral vectors for the delivery of cargo, such as the possibility of integration into a host genome by retroviral vectors, and adverse host reactions (e.g. immunological reactions) against other viral vectors, such as adenovirus. See, e.g., Yang et al., 1995, J Virol. 69:2004-2015. (see paragraph 0005). It is also noted that the ability to deliver proteins and polynucleotides to specific cell types is very useful various aspects of oncology, gene therapy etc. (see paragraph 0004)

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method of Srivastava et al. to treat patients in need thereof to with pharmaceutical compositions of human HSP90 in order to prevent the rejection of organ and tissue transplants, which would also inherently promote the fugetaxis of migratory cells in said patient at the site of transplantation and wherein the HSP90 is also attached to a targeting molecule such as a protein transduction domain which can target said HSP90 to the site required. One skilled in the art would have a

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reasonable expectation of success in doing so Robbins et al. teach many examples of the successful targeting and uptake of various polypeptides (see Examples 7-11). One skilled in the art would be motivated to use PTD's rather than viral vectors or other targeting molecules since they are safer and just as effective at delivering their cargo to the specified target site.

Hence, said claim is deemed *prima facie obvious* over the methods of Srivastava et al. and in view of Robbins et al.

Response to Arguments

11. Applicant's arguments filed 10 February 2009, with respect to the withdrawn rejection(s) as noted above are acknowledged and persuasive in view of the amendments to the claims. However, upon further consideration, a new ground(s) of rejection as noted above which necessitates the instant Office action as being a Non-Final Office action.

Conclusion

12. Claim 1 is allowed. Claims 29, 37 and 39-44 are rejected. Claim 35 is objected.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
01 May 2009